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implantor LED / handy power / handy power LED

CASTELLINI

EN

1. INTENDED USE

This is a Medical device, or a medical device accessory for professional use by Dentists, assisted by authorised office personnel.
The device is intended for use on Dental Units complying with the 93/42/EEC Directive and subsequent additions and amendments, complying with the IEC 60601-1 standard (III ed.) and installed in locations meeting the standards in force for locations for medical purposes and with an electrical plant system that complies with the IEC 60364-7-710 standard.

2. IMPORTANT WARNINGS

Before using the device read the instructions in this manual carefully. The use of the device must respect the instructions provided.
For the correct interpretation of the indications in this manual the Italian text is binding.

- The device is not suitable for use with blends of inflammable anaesthetics and oxygen or nitrous oxide.
- The instrument is provided in a non-sterile state. Before use, see to its suitable cleaning and disinfection. If the device may be sterilised, lubricate it before performing the autoclave sterilisation.
- Use of electrically-powered devices may interfere with the operation of active implantable devices such as pacemakers or other active devices. In case of doubt regarding the treatment of patients with such devices, consult a cardiology expert or another competent medical institute.
- During use of the device dust and fragments from the patient's oral cavity or from the same device may be projected into the environment (organic and inorganic dust and metal dust, fragments of the device or its tips and potentially infected biological material).
- Protect the patient, when possible, using a dental dam.
- Instruct the patient to breathe through the nose in cases where the dam is not applicable.
- Medical personnel must put on suitable personal protection equipment.
- Suitably cool the surgical field during use.
- Use only handpieces and counter angles with the CE mark of compliance with the 93/42/EEC Directive and subsequent additions and amendments.
- Use only burrs (or other similar tools) with CE Mark of compliance with Directive 93/42/EEC and subsequent additions and amendments, made with biocompatible materials complying with ISO 10993-1 and whose dimensions comply with EN ISO 1797-1 standards.
- Before each use, verify the proper locking of the handpiece onto the micro-motor and of the burr onto the handpiece chuck.
- Do not use damaged or worn handpieces.
- Make sure that during operation of the motor there is full flow of cooling air. In the absence of cooling stop using the device and call authorised technical service assistance.
- In case of visible damage, the emission of unusual noises and/or vibrations or if overheating is noticed, do not use the device and call authorised technical service assistance.
- LED radiation: do not stare into beam or view directly with optical instruments.

The manufacturer will not be held responsible regarding safety, reliability or performance of the device if:

- The essential requirements for the location, detailed in the Dental Unit User Manual are not respected;
- The assembly, the additions, the adjustments, the calibrations and/or the repairs are not performed by authorised technical service personnel;
- If modifications, tampering, incorrect maintenance have been performed, or incompatible and/or non-original spare parts have been used on the device;
- The device is not used in compliance with the use instructions and its intended use.

3. SYMBOLS

	Symbol to call the attention to other information found in the equipment User Manual.
	Symbol corresponding to “TYPE B PART APPLIED” according to IEC 60601-1. Indicates a protection grade against direct and indirect contacts.
	Part that may be sterilised in an autoclave.
	Mark of Compliance with the 93/42/EEC Directive “MEDICAL DEVICES” and subsequent additions and amendments.
	Symbol for disposal pursuant to the 2002/95/EC, 2002/96/EC, 2003/108/EC Directives.

4. TECHNICAL SPECIFICATIONS

	implantor LED	handy power handy power LED
Power supply	32 VDC	
Max absorption	6 A	6 A
Max Electrical power absorbed	170 W	170 W
Max speed	40.000 ± 10% revs/min	40.000 ± 10% revs/min
Min speed	100 ± 10% revs/min	100 ± 10% revs/min
Max torque	5,3 Ncm	3,3 Ncm
Cooling	Forced Air	
Intermittent Operation	5 min of work - 5 min of rest	
Pneumatic supply	300 ± 20 kPa (3 ± 0,2 bar)	
Water Supply	250 ± 20 kPa (2,5 ± 0,2 bar)	
Consumption	Cooling air ~ 25 Nl/min	
	Air Spray~ 5 Nl/min	
	Water Spray 35 cc/min	
Classification	Class IIa (Directive 93/42 EEC and subsequent additions and amendments) Class II type B (IEC 60601-1)	
Handpiece Connection	Compliant with ISO 3964 and compatible with INTRAmatic® Lux.	
LED Illumination	5000 K - 20000 mlm	
Applicable regulations	IEC 60601-1 – IEC 60601-1-2 – IEC 60825-1 ISO 10993-1 – EN ISO 14457	
Dimensions	47,5 mm	35 mm
Weight	79 g	66,5 g

For the correct operation of the device it must be connected to the specific power supply and electronic control circuits, designed by the manufacturer, by way of suitable connection supply tubing.
The manufacturer promises to provide, upon request, wiring diagrams, component parts lists, calibration instructions or any other information that may be needed by authorised technical service assistance personnel.
The manufacturer reserves the right to bring about modifications at any moment without notice.

5. CONNECTION TO THE POWER SUPPLY INSTRUMENT TUBING

Bring the motor next to the instrument tubing and rotate it, on the connector itself until the coupling point is found. Insert the motor completely and then fully tighten the ring nut.

6. CONNECTION AND DISCONNECTION OF THE HANDPIECE

Handpieces complying with ISO 3964 and with the INTRAmatic® Lux. type may be used. Insert the handpiece on the coupling until the connection “click” is heard.
Never mount a handpiece onto a motor that is running.
To detach the handpiece from the motor pull lightly.

7. SETTING OPERATIONAL PARAMETERS

Operational modes, speed adjustment, inversion of the rotation direction, torque adjustment, spray and LED lighting activation (if available) are to be made through the Dental Unit command panel. Refer to the Dental Unit instruction manual for the setting of the operational parameters.

8. ILLUMINATION DEVICE

In the micro-motors set up with LEDs for lighting of the surgical field, these light up automatically when the micro-motor is running.
After the motor stops, the LED remains lighted for a pre-set time. Lighting depends on settings made on the Dental Unit.

9. MAINTENANCE

At least once a week lubricate the O-Ring seals found in the handpiece coupling with silicone lubricating grease. Wearing disposable gloves, apply a film of grease on the fingertips and lubricate with the fingers.
If liquids that potentially leave incrustations are used to supply the spray, it is recommended that the circuit be flushed well with water at the end of each use.
The manufacturer requires an annual check or overhaul of the device by authorised service assistance personnel.

10. CLEANING, DISINFECTION AND STERILISATION

Before sanitisation operations, detach the handpiece from the micro-motor and the motor from the instrument tubing.
To maintain a level of hygienic security, at the end of each use and within a short time, clean, disinfect and, if applicable, sterilise the micro-motor.

Micro-motors that may be sterilised are identified by the specific symbol found in the “Symbols” paragraph.
For cleaning and/or disinfection of the outside of the micro-motor, use gauze or cotton soaked in ethyl alcohol 70% v/v.
Sterilise in a steam autoclave max 135 °C 220 kPa (2.2 bar) for 5 minutes (250 cycles tested – EN ISO 14457).

Before each autoclave cycle lubricate the micro-motor using the specific spray lubricant “DAILY OIL”, applying a quick squirt. Reconnect the motor onto the instrument tubing and activate it so as to expel the excess lubricant. Dry the outside of the micro-motor with gauze or cotton wool before proceeding on with sterilisation.

- Do not use ultrasound cleaners.
- Do not immerse the handpiece in disinfectant or sanitizing solution.
- Never sterilise the handpiece in a dry heat steriliser.
- Do not leave the handpiece in the autoclave, but remove it immediately after the cycle.
- Periodically check the autoclave according to the requirements of the manufacturer.
  Temperatures higher than the indicated limit may damage the micro-motor.

11. REPAIRS AND OVERHAULS

Installation, overhaul, calibration and repair of the device must be performed exclusively by technical service assistance personnel authorised by the manufacturer.

12. MODE OF USE

The method of application of the device is intermittent. The operational cycle indicated respects the following times:

Type of Instrument	Operation (minutes)	Pause (minutes)
implantor LED	5	5
handy power	5	5
handy power LED	5	5

13. ENVIRONMENTAL CONDITIONS FOR USE

- Ambient Temperature 10 ÷ 40 °C
- Relative Humidity 30 ÷ 75 %
- Atmospheric Pressure 700 ÷ 1060 hPa (700 ÷ 1060 mBar)

14. ENVIRONMENTAL CONDITIONS PERMITTED FOR TRANSPORT AND WAREHOUSING

- Ambient Temperature between -20 ÷ +70 °C
- Relative Humidity 10 ÷ 100 %
- Atmospheric Pressure 500 ÷ 1060 hPa (500 ÷ 1060 mBar)

15. TROUBLESHOOTING

FAULTS	PROBABLE CAUSES	INTERVENTION SUGGESTED
The motor does not turn.	Motor blocked.	Request technical service assistance.
	Blocked handpiece.	Lubricate the handpiece.
		Send the handpiece to technical service assistance.
	Electronic control board broken.	Request technical service assistance.
	Instrument tubing broken.	Request technical service assistance.
The motor runs but its speed is not adjustable.	Adjustment command broken.	Request technical service assistance.
	Electronic control board malfunction.	Request technical service assistance.
The motor functions sporadically.	Instrument tubing defective.	Substitute the instrument tubing.
	Bearings damaged.	Request technical service assistance.
The motor does not provide sufficient torque.	Torque set to its minimum.	Recover the proper adjustment.
	Endodontics mode selected.	Recover the proper adjustment.
	Power supply / motor malfunction.	Request technical service assistance.
The motor overheats.	Insufficient cooling air.	Request technical service assistance.
	Handpiece with strong friction.	Lubricate the handpiece.
		Send the handpiece to technical service assistance.
The motor turns regularly. The burr does not turn.	Handpiece not connected properly.	Slide the handpiece out and reinsert it properly.
	Handpiece broken.	Send the handpiece to technical service assistance.
	Defective transmission coupling.	Request technical service assistance.
The handpiece rotates on its coupling.	Blocked handpiece.	Send the handpiece to technical service assistance.
The handpiece does not remain inserted on the micro-motor.	Handpiece damaged.	Substitute the handpiece.
	Motor hook ring damaged.	Request technical service assistance.
Water leakage at the handpiece.	O-ring seals worn or damaged.	Substitute the O-rings.
Water leakage at the instrument tubing coupling.	O-ring seals worn or damaged.	Substitute the O-rings.

16. SCRAPPING

Scrapping the device must be carried out with respect for the laws in force for electrical and electronic equipment, according to the individual national laws.
The materials used for the manufacture are not harmful for human beings or animals that come into contact with or are exposed to them.

17. GUARANTEE CONDITIONS

The manufacturer provides the end user with a 12-month warranty, starting from the date of installation and, in any case, not exceeding 18 months from the invoice date, covering all operational faults, defects of materials or manufacture.

In case of justified complaints the manufacturer or the Authorised Repair Centre will proceed with the repair or substitution of the product free of charge.

To be able to make use of the free repair or substitution, it is an indispensable condition that, shipped together with the device, there is a proof of user's purchase document for the same device, which must include clearly legible references to the product, its serial number and date of purchase.

The guarantee expires when any damages and/or their consequences may be attributed to unsuitable procedures or modifications of the product performed by third parties not authorised by the manufacturer: that is, if non-original spare parts or components are used.

The recognition of any other claims from any origin whatsoever, in particular any requests for indemnification for damages or interest are excluded.

The manufacturer may not be held responsible for damages, or injuries and their respective consequences derived:

- From excessive wear.
- From connection of the instrument not compliant with the CE regulations.
- From improper tampering or maintenance performed by unauthorised personnel.
- From use of non-original accessories or spare parts.
- From the lack of observance of the instructions for use, for assembly or maintenance, or from improper use of the product.
- From unusual chemical, electrical or electronic influxes.
- From faulty connections (air water, electricity).

The guarantee does not cover the conductors such as the flexible “fibre optics”, nor any other elements made of synthetic materials.

18. MANUFACTURER

Manufactured by
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